M331N.PdF HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
Fax (504) 589-4657

October 7, 1997

WARNING LETTER NO. 97-NOL-65

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Karolyn S. Walker, President
Walker Wheland, Inc.
7350 Julie Frances Dr.
Shreveport, Louisiana 71129

Dear Mrs. Walker:

During an inspection of your firm, located at 7350 Julie Frances Dr., Shreveport, Louisiana, which was conducted on August 22 and September 3-5, 1997, our investigator determined that your firm manufactures manual surgical instruments and dental hand instruments. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your devices are misbranded within the meaning of Section 502(o) of the Act, in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 and was not included in a list required by Section 510(j).

Additionally, these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practices (GMPs) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate major equipment used in the manufacture of medical devices (i.e. computer-driven Kiwa mills, Mori Seiki SL2B lathe, and Citizen lathes);

2. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures;

3. Failure to establish and maintain procedures to control all required documents, which include changes, authorizations, and distribution of current, approved versions;

4. Failure to establish and maintain procedures for controlling changes to a specification, method, process, or procedure;

5. Failure to follow finished device acceptance procedures to ensure that each production run, lot or batch of finished devices meets acceptance criteria. For example, device history records are not reviewed prior to distribution of devices;

6. Failure to establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met;

7. Failure to establish procedures for and maintain records of employee training.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Until these violations are corrected, Federal agencies will be advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Barbara D. Wright, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Ave., New Orleans, Louisiana 70122-3848. Should you

have any questions concerning the contents of this letter, or if you should desire a meeting with the agency staff, you may contact Ms. Wright at (504) 589-7166.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosures: FDA-483
Device Registration & Listing Forms
Device Registration & Listing Instruction Booklet

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